**L-TOPICAL CALAMINE 8% PRAMOXINE HCL 1%- calamine, pramoxine hydrochloride lotion**
**GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

---

**L-Topical CALAMINE 8% PRAMOXINE HCL 1% LOTION**

## DRUG FACTS

### Active ingredient

Calamine 8%
Pramoxine HCl 1%

### Purpose

Skin protectant
Topical analgesic

## USES

• Temporarily relieves pain and itching associated with:
• Rashes due to poison ivy, • Poison oak or poison sumac • Insect bites • Minor skin irritation • Minor cuts • Dries the oozing and weeping of poison ivy, poison oak and poison sumac

## WARNINGS

**For external use only.**

**When using this product** do not get into eyes

**Stop use and ask a doctor if**
• Condition worsens or does not improve within 7 days
• Symptoms persist for more than 7 days or clear up and occur again within a few days

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

## DIRECTIONS

• Shake well before use • Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily • Children under 2 years of age: ask a doctor

## OTHER INFORMATION

Store at 20° to 25°C (68° to 77°F)

## INACTIVE INGREDIENTS

SD Alcohol 38-B, Camphor, Diazolidinyl urea, Fragrance, Hypromellose, Methylparaben, Polysorbate 80, Propylene glycol, Propylparaben, Purified water, Xanthan gum

## QUESTIONS/COMMENTS

Call toll-free 1-800-572-6632, Weekdays 7:00 AM - 5.30 PM EST.

**Calamine Plus Itch Reliever**

Manufactured by :

**Global Pharma Healthcare Pvt. Ltd.,**

A-9, SIDCO Pharmaceutical Complex,

Alathur-603 110 - INDIA.

**www.global-pharma.com**

## Packaging


## L-TOPICAL CALAMINE 8% PRAMOXINE HCL 1%

calamine, pramoxine hydrochloride lotion

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:73921-036 |

| | |
|---|---|
| **Route of Administration** | TOPICAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ZINC OXIDE** (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 80 mg in 1 mL |
| **PRAMOXINE HYDROCHLORIDE** (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056) | PRAMOXINE HYDROCHLORIDE | 10 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ALCOHOL** (UNII: 3K9958V90M) | |
| **CAMPHOR (SYNTHETIC)** (UNII: 5TJD82A1ET) | |
| **DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **XANTHAN GUM** (UNII: TTV12P4NEE) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:73921-036-04 | 118 mL in 1 CONTAINER; Type 0: Not a Combination Product | 04/01/2021 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part347 | 04/01/2021 | |

## Labeler - GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED (860186917)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED | | 860186917 | manufacture(73921-036) |

Revised: 3/2021 GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED